K121085

NOV 20 2012

510(k) SUMMARY
(Per 21 CFR 807.92)

General Company Information

Name: HET Systems, LLC
Contact: Howard Schrayer
Regulatory Affairs Consultant

Address: 113 Laredo Drive
Morganville, NJ 07751

Telephone: (609) 924-9510
E-mail: hs.ss@verizon.net

Date Prepared November 20, 2012

General Device Information

Product Name: HET™ Bipolar Electrocautery Forceps and Monitor

Classification: "Electrosurgical cutting and coagulation device and accessories"
Product code: GEI - Class II
21 CFR 878.4400

Predicate Devices

HET™ Bipolar Electrocautery Forceps and Monitor
HET Systems, Inc.
510(k) K110143

Redfield Infrared Coagulator
Redfield, Inc.
510(k) K950836

Description

The HET™ Bipolar Electrocautery System is comprised of the HET™ Bipolar Forceps and the HET™ Monitor.

The HET™ Bipolar Forceps is a sterile, single-use bipolar forceps having a tapered tubular configuration. The device is connected via an integrated bipolar cable to the bipolar output of an electrosurgical generator.

When connected to the HET™ Monitor, the HET™ Bipolar Forceps has an integrated tissue illumination feature and a temperature probe. The HET™ Monitor is an accessory that can be used only with the HET™ Bipolar Forceps when used in conjunction with the CONMED HYFRECATOR® 2000 or the VALLEYLAB SURGISTAT II RF generators. The monitor displays the temperature at the forceps-tissue interface. The HET™ Monitor does not generate RF energy.

Intended Use (Indications)

The HET™ Bipolar Electrocautery Forceps and Monitor is intended to be used for grasping, manipulating and coagulating soft tissue during general surgery.

The HET™ Bipolar Electrocautery System may be used for the treatment of symptomatic Grade I and Grade II internal hemorrhoids.

The accessory monitor provides power for a temperature sensor and an LED light source mounted on the disposable forceps. The HET Bipolar Electrocautery Forceps and Monitor may be used with the CONMED HYFRECATOR® 2000 or VALLEYLAB SURGISTAT II RF energy generators.

Substantial Equivalence

This submission supports the position that the HET™ Bipolar Electrocautery Forceps is substantially equivalent to a number of previously cleared devices, including the previously cleared HET Bipolar Electrocautery Forceps and Monitor (K110143) and the Redfield Infrared Coagulator (K950836).

The technological characteristics of the device are unchanged (exactly the same as) the characteristics of the predicate HET Systems device that was cleared under 510(k) K110143, with the exception that the timing indicator has been removed from the Monitor. Specifically, the materials, software, and treatment mechanism (i.e., bipolar energy used to produce heat) are unchanged.

The technological characteristics of the device differ from those of the Redfield Infrared Coagulator (IRC) predicate that was cleared under 510(k) K950836 in regard to the materials used and energy source. The IRC device uses infrared light to produce heat, instead of high frequency bipolar energy. However, both predicate systems and the subject device use thermal energy to achieve the treatment effect (tissue coagulation). The IRC predicate is indicated for the treatment of internal hemorrhoids.

The 510(k) Notice contains a report of a study (in an animal model) that was conducted to evaluate the *in vivo* performance and histological effects of the device as compared to the predicate device. Biocompatibility studies, software validations, and electrical safety studies were conducted and reported in the 510(k) Notice for the predicate HET Systems device. Because the two devices are essentially the same, the information reported for the predicate HET device is applicable.

The 510(k) Notice also contains reports of two human clinical evaluations that were conducted to evaluate the clinical performance of the device. These studies demonstrated outcomes substantially equivalent to clinical outcomes reported in the literature for the predicate IRC device.

Conclusions

HET Systems, LLC believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the indications for the HET™ Bipolar Electrocautery Forceps and Monitor. The material from which the HET Systems device is fabricated has an established history of use in medical applications; and devices produced by HET Systems have been tested in accordance with applicable guidelines and standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

HET Systems, LLC
% HET Bipolar Ligator System
Mr. Howard Schrayer
Regulatory Affairs Consultant
113 Laredo Drive
Morganville, NJ 07751

Letter Dated: November 20, 2012

Re: K121085
Trade/Device Name: HET™ Bipolar Electrocautery Forceps and Monitor
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 09, 2012
Received: November 13, 2012

Dear Mr. Schrayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K121085

Device Name: HET™ Bipolar Electrocautery Forceps and Monitor

Indications For Use:

The HET™ Bipolar Electrocautery Forceps and Monitor are intended to be used for grasping, manipulating and coagulating soft tissue during general surgery.

The HET™ Bipolar Electrocautery Forceps and Monitor may be used for the treatment of symptomatic Grade I and Grade II internal hemorrhoids.

The accessory monitor provides power for a temperature sensor and an LED light source mounted on the disposable forceps. The HET Bipolar Electrocautery Forceps and Monitor may be used with the CONMED HYFRECATOR® 2000 or VALLEYLAB SURGISTAT II RF energy generators.

Prescription Use ___X_____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K 121085